REMARKS

Reconsideration and allowance are respectfully requested.

Claims 22-24, 26-33, 35-38 and 40-51 are pending. Rejoinder of the withdrawn claims is requested upon an indication that a generic claim is allowable.

The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. For example, typographical errors and other informalities are corrected and clarity is improved in the claims. The claims are limited to first and second means that are cells. Support for this narrowing amendment is found in the claims as originally filed which specifically recite "cells" (e.g., mammalian cells and yeast). The means-plus-function language is deleted. Therefore, to the extent that the Examiner was relying on Section 112, sixth paragraph, to interpret the previous claims, such reliance is no longer proper. New claims 50-51 are based on pending claims 22 and 41, but the former claims recite an intended use of the immunogenic composition and sera or antibody for recognition of an infectious pathogenic agent.

The specification was objected to on pages 2-3 of the Action. Another sequence listing with the complete human sequence of CCR5 is submitted herewith in response to the Examiner's requirement. The nucleotide sequence of SEQ ID NO:23 was obtained from GenBank accession number NM_000579; the specification was amended at page 13 to add the sequence identifier. Therefore, no new matter is added by inserting this sequence into the record of the application. The other sequences on pages 17-19 were included in the original sequence listing and their sequence identifiers were inserted by amendment on August 19, 2003.

Withdrawal of the objection is requested.

35 U.S.C. 101 –Utility

Only after the Patent Office provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility. *In re Brana*, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995).

Claims 22 and 42 were rejected as allegedly "being inoperative and therefore lacking patentable utility." Applicant traverses.

It was alleged on page 3 of the Action that the claimed invention is inoperative. No evidence contradicting this utility was provided in the Action. Therefore, the burden of proof has not shifted to Applicant. We do agree with the Examiner that antibodies preventing infection by a pathogenic agent would also recognize it. The Section 101 rejection made in the Action mailed May 22, 2006 was directed against (i) the lack of the term "isolated" in claim 41 and (ii) recitation of "a vaccine composition" in claims 22 and 42. Both concerns were addressed by the amendment of the claims filed October 23, 2006. It was also stated on page 8 of the Action that the specification is enabling for an immunogenic composition. This admission appears to have been overlooked by the new examiner even though M.P.E.P. § 704.01 instructs examiners that "full faith and credit should be given to the search and action of the previous examiner unless there is a clear error in the previous action or knowledge of other prior art." Here, no evidence of either clear error or knowledge of other prior art was provided.

Although the Patent Office has not provided evidence to shift the burden of proof, Applicant submits that his specification does support a credible statement of utility. The claimed "immunogenic composition" is directed to a product. The Examiner admitted that recognition of an infectious pathogenic agent by Applicant's invention is useful and enabled. Thus, the evidence of record establishes that the product claims may be used (at least) to elicit an antibody that recognizes the pathogenic agent. This aspect of the invention is sufficient to prove utility. Whether or not the immunogenic composition would function as a vaccine or would elicit neutralizing antibodies is irrelevant to reconsideration of this rejection because there are other immunogenic uses for the invention.

Withdrawal of the Section 101 rejection is requested because Applicant has taught that the claimed invention has a credible utility.

35 U.S.C. 112 – Enablement

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent

upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claims 22 and 42 were rejected under Section 112, first paragraph, because they allegedly contain "subject matter which was not described in the specification commensurate in scope." Applicant traverses.

As noted above, claims 22 and 42 are directed to an immunogenic composition that can elicit specific antibodies against the immunogen (and an infectious pathogenic agent). They do not require that a vaccine be provided; they also do not require that a neutralizing antibody be elicited by the immunogen. It was admitted on page 8 of the Action mailed May 22, 2006 that the specification is enabling for an immunogenic composition. Therefore, Applicant's enabling disclosure is commensurate in scope with the pending claims.

Withdrawal of the enablement rejection made under Section 112, first paragraph, is requested because it would not require undue experimentation for a person of skill in the art to make and use the claimed invention.

35 U.S.C. 102 – Novelty

A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosure cited as prior art is not enabled. *Amgen v. Hoechst Marion Roussel*, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003); See *Bristol-Myers Squibb v. Ben Venue Laboratories*, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) ("To anticipate the [prior art] reference must also enable one of skill in the art to make and use the claimed invention"). The prior art reference must sufficiently describe the claimed invention to have placed the public in possession of it; such possession is effected if one of ordinary skill in the art could have combined the prior art's description of the invention with his own knowledge to make the claimed invention. *Elan Pharms. v. Mayo Found.*, 68

USPQ2d 1373, 1376 (Fed. Cir. 2003); *In re Donohue*, 226 USPQ 619, 621 (Fed. Cir. 1985).

Claims 22-24, 26-37, 41 and 44 were rejected under Section 102(b) as allegedly anticipated by LaCasse et al. (Science, 283:357-362, 1999). Applicant traverses since the cited reference's conclusion that serum raised against their immunogen contains neutralizing antibodies was subsequently retracted by the senior author (see the copy of Nunberg's letter in Science, 296:1025, 2002; which is attached).

The LaCasse et al. reference was cited in the Action, but it appears that the Examiner was not aware of the retraction of their "published results" after "a specific cytotoxic effect" was discovered in the sera elicited after immunization. The contribution of antibodies against the immunogen was not measured (e.g., "This unappreciated cytotoxicity significantly reduces both the potency and the breadth of primary virus neutralization"). Nunberg admitted, "The basis for the specific cytotoxic effect is unknown" in his letter. Since the origin of this artifact was not explained and the skilled artisan would not have been able to eliminate it based on the evidence of record, undue experimentation would have been required to practice what was disclosed in the cited reference. Thus, the public was not put in possession of the claimed invention by LaCasse et al.

Claims 22, 26, 29-30 and 36-37 were rejected under Section 102(a) as allegedly anticipated by Schønning et al. (Ugeskr Laeger, 161:4415-4416, 1999). Applicant traverses because this reference is not prior art. As requested by the Examiner on page 5 of the Action, an English translation of the foreign priority document is submitted herewith. Acknowledgement is requested that the claims are entitled to the benefit of the earliest claimed priority date.

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 22, 31, 38-39 and 41 were rejected under Section 102(b) as allegedly anticipated by DeVico et al. (Virology, 211:583-588, 1995). Applicant traverses.

Claim 22 is amended to exclude complexes formed between an isolated CD4 molecule and isolated monomeric gp120 as disclosed in DeVico et al. Therefore, the cited reference does anticipate the claimed invention.

Claims 22, 31, 38-39 and 41 were rejected under Section 102(b) as allegedly anticipated by Kwong et al. (Nature, 393:648-659, 1998). Applicant traverses.

Claim 22 is amended to exclude complexes formed between an isolated CD4 molecule and isolated monomeric gp120 as disclosed in Kwong et al. Therefore, the cited reference does anticipate the claimed invention.

Withdrawal of the Section 102 rejections is requested because the cited prior art references fail to enable the claimed invention or to disclose all limitations of the claims.

35 U.S.C. 103 – Nonobviousness

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing the legal standard provided in *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d 1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. See id. ("Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue"). The use of hindsight reasoning is impermissible. See id. at 1397 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning"). Thus, a rejection under Section 103(a) requires "some rationale, articulation, or reasoned basis to explain why the conclusion of [prima facie] obviousness is correct." *Kahn*, 78 USPQ2d at 1335; see *KSR*, 82 USPQ2d at 1396.

Claims 22, 25 and 41 were rejected under Section 103(a) as allegedly unpatentable over DeVico et al. (Virology, 211:583-588, 1995) or Kwong et al. (Nature, 393:648-659, 1998) in view of Rigaud et al. (Biochem. Biophys. Acta, 1231:223-246, 1995). Applicant traverses.

The failure of DeVico et al. and Kwong et al. to disclose the claimed invention is not remedied by the attempt to combine those disclosures with Murphy et al. As noted above, the DeVico et al. and Kwong et al. references are limited to forming complexes between isolated molecules. Applicant's invention requires complex formation between cells. Applicant submits that these defects in the obviousness rejection are sufficient to establish patentability over the cited references so any other incorrect allegations about their disclosures are not disputed here, but the opportunity to dispute them in the future is reserved.

Claims 22 and 40 were rejected under Section 103(a) as allegedly unpatentable over LaCasse et al. (Science, 283:357-362, 1999) in view of Rissio et al. (J. Virol., 72: 7992-8001, 1998). Applicant traverses.

The failure of LaCasse et al. to disclose the claimed invention is not remedied by the attempt to combine that disclosure with Rissio et al. As noted above, the LaCasse et al. reference is not enabled for the disclosure relied upon by the Examiner. Applicant submits that this defect in the obviousness rejection is sufficient to establish patentability over the cited references so any other incorrect allegations about their disclosures are not disputed here, but the opportunity to dispute them in the future is reserved.

Claims 22-24, 26-40 and 41 were rejected under Section 103(a) as allegedly unpatentable over LaCasse et al. (Science, 283:357-362, 1999) in view of Riley et al. (J. Virol., 72:8273-8280, 1998). Applicant traverses.

The failure of LaCasse et al. to disclose the claimed invention is not remedied by the attempt to combine that disclosure with Riley et al. As noted above, the LaCasse et al. reference is not enabled for the disclosure relied upon by the Examiner. Applicant submits that this defect in the obviousness rejection is sufficient to establish patentability over the cited references so any other incorrect allegations about their disclosures are not disputed here, but the opportunity to dispute them in the future is reserved.

Claims 24, 43-44 and 47 were rejected under Section 103(a) as allegedly unpatentable over LaCasse et al. (Science, 283:357-362, 1999) in view of Murphy et al. (Genet. Anal. Tech. Appln., 7:160-171, 1990). Applicant traverses.

The failure of LaCasse et al. to disclose the claimed invention is not remedied by the attempt to combine that disclosure with Murphy et al. As noted above, the LaCasse et al. reference is not enabled for the disclosure relied upon by the Examiner. Applicant submits that this defect in the obviousness rejection is sufficient to establish patentability over the cited references so any other incorrect allegations about their disclosures are not disputed here, but the opportunity to dispute them in the future is reserved.

Withdrawal of the Section 103 rejection is requested because the claimed invention would not have been obvious to the ordinarily skilled artisan at the time Applicant made his invention.

Conclusion

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicant submits that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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